

REMARKS

Applicants respectfully request entry of the amendments hereinabove, and an early examination and allowance of the claims.

Specifically, Applicants request entry of the claim for priority and acknowledgment of such claim.

Claim 1 is included as original.

Applicants submit that the amendments to the existing claims and newly added claims 48-56 are fully supported.

Applicant further submits that the literal basis for such amendment is not required to be found in the specification (the claim phrase need not be "*in haec verba*" in the specification) *In Re Wright* 9 U.S.P.Q.2d 1649, 1651 (Fed. Cir. 1989); *Crowne Operations, Int'l, Inc. v. Solutia, Inc.* 289 F.3d 1367, 1376 (Fed. Cir. 2002).

Claims 39, 42 and 45 have been amended as independent claims to recite the Formula I genus claim (in place of the reference to a compound of Claim 1). Support for this amendment may be found in original claim 1 as filed and amended resulting in the parent patent U.S. pat. No. 6,197,786. In addition, claims 39, 42 and 45 have been amended to claim fibrates as a combination agent. Support for these amendments may be found in original claims 39, 42 and 45 and page 58, line 32.

Applicants have corrected an obvious clerical error to the supporting subject matter that is repeated in claims 39, 42 and 45. Specifically Applicants have amended the description of Q<sup>1</sup> by adding the verb "is" to the phrase "wherein Q<sup>1</sup> a fully saturated, partially unsaturated or fully unsaturated..." to read "wherein Q<sup>1</sup> **is** a fully saturated, partially unsaturated or fully unsaturated..." .

Further, claim 39, line 5 has been amended to correct an obvious clerical error by replacing the term product with prodrug. Also, claim 39 has been amended to recite "pharmaceutically acceptable" in place of "pharmaceutical".

Support for this may be found on page 71, line 8 of the specification. Claim 39 has also been amended to recite a "vehicle or diluent" in addition to the carrier previously recited. Support for this may be found on page 71, line 8 of the specification.

Claim 45 has been amended to recite a "vehicle or diluent" in addition to the carrier previously recited. Support for this may be found on page 71, line 8 of the specification.

Claims 40, 43 and 46 have been cancelled.

Claims 41, 44 and 47 have been amended to claim an additional combination agent atorvastatin. Page 58, lines 27-29 provides support for claiming additional agents. The use of the agent atorvastatin is supported by page 59 lines 3-4 and 21-22 (atorvastatin).

Newly added claims 48, 49 and 50 are dependent from claims 39, 42 and 45 respectively and are directed to claims wherein the Formula I compound is 4(S)-[(3,5-bis-trifluoromethyl-benzyl)-methoxycarbonyl-amino]-2(R)-ethyl-6-trifluoromethyl-3,4-dihydro-2H-quinoline-1-carboxylic acid ethyl ester. Support for claims 48, 49 and 50 may be found in Example 118 and original claim 17.

Newly added claims 51, 52 and 53 are dependent from claims 41, 44 and 47 respectively and are directed to claims wherein the Formula I compound is 4(S)-[(3,5-bis-trifluoromethyl-benzyl)-methoxycarbonyl-amino]-2(R)-ethyl-6-trifluoromethyl-3,4-dihydro-2H-quinoline-1-carboxylic acid ethyl ester. Support for claims 51, 52 and 53 may be found in Example 118 and original claim 17.


Newly added claims 54, 55 and 56 are analogous to claims 51, 52, and 53 except atorvastatin calcium is recited. Support for atorvastatin calcium may be found in the instant application page 59, lines 20-22. "In addition, U.S. Pat. No. 5,273,995 (the disclosure of which is incorporated by reference) discloses certain 6-[2-(substituted-pyrrol-1-yl)alkyl]pyran-2-ones such as

atorvastatin." In U.S. pat. no. 5,273,995 the compound known as "atorvastatin calcium" "Lipitor<sup>R</sup>), is listed, for example, by chemical name on column 3, lines 3-6 as [R-(R\*R\*)]-2-(4-fluorophenyl)- $\beta,\delta$ -dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid, hemicalcium salt.

Please charge any additional fees which may be required, or credit any overpayment, to Deposit Account No. 16-1445. Two copies of this sheet are enclosed.

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Respectfully submitted,



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